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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/779,721	02/18/2004	Jerry Jonn	118560	1723

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EXAMINER	
NEAL, TIMOTHY J	
ART UNIT	PAPER NUMBER
3731	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/09/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/779,721	JONN ET AL.	
	Examiner	Art Unit	
	Timothy J. Neal	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 November 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6,11-29 and 31-55* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6, 11-29, 31-55* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This action is response to Applicant's amendment received on 11/21/2006.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-6, 11-23, 25, 34-39, and 41-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clark et al. (US 5,259,835) in view of Ballance et al. (US 6,439,789).

Clark discloses:

Claim 1: a flexible material (Fig 1 Item 30 and Fig 10 Item 30 and Fig 6); an adhesive substance applied over substantially the entire bottom side of said flexible material (Fig 2 Item 40); and an adhesive composition permeated throughout at least a portion of said flexible material (Col 4 Line 14).

Claim 2 and 47: said flexible material is a mesh (Col 3 Line 54).

Claim 3: said flexible material comprises perforations or tear lines (Fig 6 Item 52).

Claim 4: said flexible material is flexible and porous (Col 3 Line 35 and Col 3 Line 54).

Claim 5: said flexible material is substantially free of elastin (not stated in disclosure as being present or required for this device).

Claim 6: said flexible material is elastic (Col 3 Line 34).

Claim 11 and 48: said adhesive substance is a pressure sensitive adhesive (Col 4 Line 45, stated as well known in the art by the reference and by the Applicant (paragraph 49 of Specification).

Claim 12 and 49: said pressure sensitive adhesive has a weaker bonding strength than said adhesive composition (Col 4 Line 33).

Claim 13: said adhesive substance does not interact with said adhesive composition (Fig 10).

Claim 18: said adhesive composition substantially covers surfaces on at least said bottom side and a top side of said flexible material (Fig 10).

Claim 19: said adhesive composition substantially does not cover said adhesive substance (Fig 10).

Claim 25: the flexible material is not biodegradable (Col 3 Line 40; polyolefins are considered generally to be non-biodegradable).

Claim 31: said adhesive substance is permeated by said adhesive composition (Col 4 Line 38).

Claim 32: said flexible substrate (does) not include features that penetrate an underlying substrate during use (Fig 8 Item 56). A barrier layer to prevent the flow of adhesive into the wound is described. The barrier layer may be used with any of the embodiments, therefore, it would have been obvious to a person having ordinary skill in

the art at the time the invention was made to modify any of Clark's embodiments to include the barrier layer. Such a modification would prevent the adhesive from flowing into the wound.

Claim 33: one or more adhesive strips attached to the flexible material, wherein the adhesive substance is provided on the one or more adhesive strips (Fig 2 Item 40).

Claim 34: a method of bonding tissue, comprising: placing a flexible substrate over a section of tissue, wherein said flexible substrate comprises a flexible material and an adhesive substance applied over substantially the entire bottom side of said flexible material (Col 4 Line 14); applying an adhesive composition over and substantially covering at least a portion of the flexible substrate (Col 4 Line 14); and allowing the adhesive composition to permeate into and under the flexible substrate and polymerize to form a composite structure bonded to said tissue (Figs 10 and 19).

Claim 35: said section of tissue includes a wound to be closed (Figs 10 and 19).

Claim 36: said placing comprises: fixing a first portion of said flexible substrate to said section of tissue on a first side of said wound; approximating edges of said wound; and fixing a second portion of said flexible substrate to said section of tissue on a second of said wound opposite said first side of said wound (Figs 10 and 19).

Claim 37: removing said first and second portions of said flexible substrate (Figs 10 and 19).

Claim 38: a third portion of said flexible substrate remains, covering said wound (Figs 10 and 19).

Claim 39: said removing comprises trimming said first and second portions of said flexible substrate (Col 8 Line 23).

Claim 41: said applying comprises: placing a quantity of said adhesive composition on an exposed side of the flexible substrate; and spreading the quantity of adhesive composition to substantially cover the flexible substrate (Fig 19 and Col 3 Line 50).

Claim 42 and 55: said section of tissue has a length and a width, said length being longer than said width; said wound has a length and a width, said length being longer than said width; and said wound extends lengthwise in a lengthwise direction of said section of tissue (Fig 19).

Claim 43: the flexible material is sterilized (Col 9 Line 30).

Claim 44: the adhesive composition is sterilized (Col 9 Line 43).

Claim 45: wherein said polymerizable adhesive composition interacts with and/or solubilizes said adhesive substance (Fig 2).

Claim 46: a flexible material (Fig 1 Item 30 and Fig 10 Item 30 and Fig 6); an adhesive substance applied over at least a portion of a bottom side of said flexible material (Fig 2 Item 40); and an adhesive composition applied over an entire surface of said flexible material and permeated throughout at least a portion of said flexible material (Col 4 Line 14).

Claim 54: a method of bonding tissue, comprising: placing a flexible substrate over a section of tissue, wherein said flexible substrate comprises a flexible material and an adhesive substance applied over at least a portion of a bottom side of said

flexible material (Col 4 Line 14); applying an adhesive composition over and substantially covering an entire surface of the flexible substrate (Col 4 Line 14); and allowing the adhesive composition to permeate into and under the flexible substrate and polymerize to form a composite structure bonded to said tissue (Figs 10 and 19).

Regarding claims 1-44, specifically claims 1, 14-17, 20-29, 40, 46, and 50-54 Clark does not disclose the adhesive being polymerizable, a polymerization initiator or rate modifier for said polymerizable adhesive composition disposed in or on said flexible material; said polymerization initiator or rate modifier is immobilized on said flexible material; a bioactive material disposed in or on said flexible material; said bioactive material is not immobilized on said flexible material, but is soluble or dispersible in said polymerizable adhesive composition; the flexible material is biodegradable; the flexible material is not biodegradable; the flexible material and the polymerizable adhesive composition are together biodegradable; the flexible material and the polymerizable adhesive composition are together not biodegradable; the article is opaque; the article is translucent; said placing comprises: fixing a first lengthwise end of said flexible substrate to said section of tissue on a first lengthwise end of said wound; approximating edges of said wound; and fixing a second lengthwise end of said flexible substrate to said section of tissue on a second lengthwise end of said wound opposite said first lengthwise end of said wound.

Regarding claims 1-23, 25, 34-39, 41-44, and 46-55, Ballance teaches a 1,1-disubstituted monomer and a cyanoacrylate monomer that are both polymerizable (Col 6 Lines 35-53). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Clark's adhesive to include Ballance's polymerizable adhesive. Such a modification would provide protective coverage of wounds with a fast-acting surgical adhesive.

Ballance also teaches the use of a polymerization initiator and bioactive material (Col 6 Lines 55-65). Ballance also teaches the initiator being immobilized (Fig 1 Item 120) and the bioactive material being dispersible in the polymerizable composition (Col 7 Line 20). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Clark's article to include Ballance's polymerizable initiator and bioactive material. Such a modification would accelerate polymerization and the use of bioactive agents can help the healing process. By keeping the initiator immobilized, the polymerizable adhesive will avoid polymerizing until the desired time, for example, not until after the bandage is in place. The bioactive material being dispersible in the polymerizable composition allows it to reach the wound so that it can be effective.

Claims 24, 26, 28, and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clark et al. (US 5,259,835) and Ballance et al. (US 6,439,789) in view of Porzilli (US 5,336,209).

Clark and Ballance disclose the invention substantially as claimed as stated above and do not disclose the specific limitations as stated above.

Regarding **claims 24, 26, 28, and 29**, Porzilli teaches an opaque or translucent bandage that is biodegradable (Claims 5, 13, and 14 and Col 2 Line 35). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Clark and Ballance's article to include Porzilli's translucent or opaque biodegradable characteristics. Such a modification would either prevent the wound from being seen or allow limited visualization of the wound. A biodegradable substance will degrade overtime and not need to be removed. Cyanoacrylate is a biodegradable adhesive, so the combination of Porzilli's biodegradable bandage with the cyanoacrylate adhesive as discussed above would satisfy the limitations of claim 26. Also, the Examiner notes that the Applicant has admitted that biodegradable and non-biodegradable adhesives are known in the art (Paragraph 33 of Specification), so upon argument that cyanoacrylate is not biodegradable, the rejection will stand that it would have been obvious to a person having ordinary skill in the art to combine Porzilli's biodegradable material with one of the known biodegradable adhesives so that the article will not need to be removed and is environmentally friendly.

Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Clark et al. (US 5,259,835) and Ballance et al. (US 6,439,789).

Clark and Ballance disclose the invention substantially as claimed as stated above and do not disclose the specific limitations as stated above.

Regarding **claim 27**, the Applicant has admitted that biodegradable and non-biodegradable adhesives are known in the art (Paragraph 33 of Specification). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Clark and Ballance's article to include a non-biodegradable polymerizable adhesive composition. Such a modification would require the bandage to be removed from the wound. This would allow the user to keep the article on the wound until the wound is completely healed. A biodegradable composition may biodegrade prior to complete healing.

Claim 40 is rejected under 35 U.S.C. 103(a) as being unpatentable over Clark et al. (US 5,259,835) and Ballance et al. (US 6,439,789) in view of Vandruff (US 2002/0193721).

Clark and Ballance disclose the invention substantially as claimed as stated above and do not disclose the specific limitations as stated above.

Vandruff teaches said placing comprises: fixing a first lengthwise end of said flexible substrate to said section of tissue on a first lengthwise end of said wound; approximating edges of said wound; and fixing a second lengthwise end of said flexible substrate to said section of tissue on a second lengthwise end of said wound opposite said first lengthwise end of said wound (Figs 9 and 10). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to

modify the method of Clark and Ballance to include Vandruff's placing step. Such a modification would cover a wound in the lengthwise direction with a single article.

Response to Arguments

Applicant's arguments filed 11/21/2006 have been fully considered but they are not persuasive.

The Applicant has argued that the prior art fails to disclose and/or teach the adhesive substance applied over substantially the entire bottom side of said flexible material. The Examiner considers the prior art of record to meet this limitation. The Clark reference discloses strips of adhesive deposited over the entire bottom side. The word "over" does not limit the claim or the prior art to an adhesive substance that covers or is in contact with the entire bottom surface of the flexible material. Also, the word "over" generally means "on top" or "above". The adhesive of Clark is over the entire bottom side of the flexible material in that the material has been applied on top of the bottom side. There is no portion of the entire bottom side that extends beyond the extent of the adhesive. The bottom side is broadly interpreted as the side applied to the wound and is not necessarily directional (the orientation of the article can change, but the bottom side will remain the bottom side). When the article is upside down, for example when placed under the chin, the adhesive would be over the entire bottom side. The Examiner considers the Applicant's argument to be based on a narrow interpretation of the word "over".

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

The Examiner notes that the Applicant does admit that biodegradable polymerizable adhesive compositions are known in the art (Paragraph 33). Also, the Examiner considers the advantages of biodegradable materials to be well known in the art. The Examiner stated that making materials biodegradable is environmentally friendly. The advantage stated has been known and would have been an obvious advantage well before the Applicant's disclosure. Making a tissue-bonding article biodegradable, such as a bandage, would not only be beneficial while on the wound (so that the bandage need not be removed), but also should the bandage be removed. Once removed, the article would be environmentally friendly. Because the polymerizable adhesive composition is part of the bandage after being applied, it would be obvious, for the advantage of being environmentally friendly, to use a biodegradable adhesive. Therefore, making both the polymerizable adhesive and the flexible material biodegradable would have been obvious to one having ordinary skill in the art. If the Applicant is arguing that there is no teaching or explanation for making the materials

biodegradable together wherein together refers to degrading at the same time, the Examiner considers this too narrow of an interpretation of the word "together". The claim should be amended to state that the materials degrade at the same rate or simultaneously.

The Applicant has argued that the there is no motivation to combine VanDruff and Clark because of the different ways in which they heal wounds. The claim is directed at a method of bonding tissue. The Examiner considers the references combinable with motivation because the combination provides an improved method for bonding tissue. The Clark reference provides a long-term means for wound healing via the adhesive. The VanDruff reference provides a substrate designed to heal wounds of a lengthwise nature. The "stitching" of VanDruff is well suited for providing apposition across the entire length of the wound. Clark is more concerned with long-term healing of a wound by means of the adhesive; however, in one embodiment (Fig 26) Clark does show the device being used with a lengthwise wound. This particular embodiment contains multiple pieces making the device somewhat difficult to use. The Vandruff article can be applied as one piece in the manner claimed (see Paragraph 43). Therefore, the Examiner considers the combination of these references to provide advantages that would have been apparent from the disclosures. The Clark device provides a longer-term means for wound healing by use of an adhesive. The VanDruff device and method provides a means for apposition of a lengthwise wound that involves the simplicity of only a single article and the ability to place the wound edges in apposition when the wound is of some length. Therefore, the advantage of combining

these two references is to provide a method using the long-term characteristics of Clark's adhesive with the simplicity and increased applicability of VanDruff's device and method. Without Vandruff's teaching, the Clark reference does suggest use on a lengthy wound, but this includes the use of multiple members complicating the process.

Claims 46-55 have been added based on the prior art not having a polymerizable adhesive composition applied over an entire surface of said flexible material. The Examiner considers the prior to read on these added claims. A "surface" is generally viewed as the outer or the topmost boundary of an object and a material layer constituting such a boundary. The Applicant has not defined any boundaries to limit the "surface" as claimed. Furthermore, because the surface has not been limited by any boundaries, the "entire surface" is also not limited. The Examiner considers the Clark reference to disclose as stated above, that the adhesive flow to a surface of the material. The entirety of that surface is then covered as claims 46 and 54 indicate. Without defining or further limiting the boundaries of the surface to be covered, the Examiner considers the prior art to read on the claims.

The Examiner considers the above explanation to address all of the Applicant's arguments. Any further arguments were based on the dependency of the claim from a contested claim rejection.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Buchanan et al (US 5,599,858) discloses biodegradable

bandages as being environmentally friendly. Holmbald et al. (US 5,173,302) discloses a bandage with a layer of adhesive (Item 13) in contact with the entire bottom surface of a bandage with a layer of adhesive permeated through a flexible material (Fig 2).

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Timothy J. Neal whose telephone number is (571) 272-0625. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TJN

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1/4/07